UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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AMGEN INC.,

Plaintiff,

-against-

NOVARTIS PHARMA AG,

Defendant.

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Case No. 1:19-CV-3003

COMPLAINT

JURY TRIAL DEMANDED AS TO ALL ISSUES TRIABLE BY JURY

NATURE OF THE CASE

1. Novartis Pharma AG has materially breached its multi-billion-dollar contract with Amgen to develop and commercialize Amgen's migraine medication called erenumab or Aimovig®, by simultaneously helping to bring a competing medication to market.

2. In 2015 and 2017 contracts, Novartis agreed to collaborate with Amgen in developing and commercializing erenumab. Novartis promised not to directly or indirectly, itself or through any Affiliate, take part in the clinical development, commercialization, or manufacture of other calcitonin gene-related peptide (CGRP) inhibitor therapies. And in 2017, Amgen and Novartis agreed that Novartis's Sandoz division was an Affiliate for purposes of this promise.

3. Unbeknownst to Amgen, in negotiating this agreement Novartis was already violating its promise because since 2015 Sandoz has helped Alder BioPharmaceuticals to develop, commercialize, and manufacture a competing CGRP therapy called eptinezumab. Amgen has demanded that Novartis cure this material breach. But Novartis has not done so. Sandoz continues to manufacture eptinezumab for Alder, and has even guaranteed Alder that it will continue to do so for several more years. Amgen therefore seeks to terminate its collaboration agreements with Novartis and requests damages resulting from Novartis's material breach of contract.

OVERVIEW

4. The contractual relationship at issue here consists of two interrelated contracts that Novartis Pharma AG signed in 2015 and 2017 to gain access to a portion of the huge market Amgen's CGRP inhibitor migraine therapies promised: (1) the Exclusive License and Collaboration Agreement By and Between Amgen Inc. and Novartis Pharma AG, effective August 28, 2015 and amended April 21, 2017 (referred to herein as the "2015 Agreement"), and (2) the U.S. Collaboration Agreement By and Between Amgen Inc. and Novartis Pharma AG, effective April 21, 2017 (referred to herein as the "2017 Agreement"). These two contracts—collectively referred to herein as the "Collaboration Agreements"—spell out the details of how Amgen and Novartis agreed to collaborate in developing and commercializing Amgen's proprietary CGRP inhibitor therapies, including the migraine treatment medication erenumab, which is now known in some parts of the world by the brand name Aimovig®.

5. In the 2015 Agreement, Novartis agreed to develop and commercialize erenumab with Amgen outside of the United States, Japan and Canada. Among other things, the 2015 Agreement memorializes the parties' commitment to broadly restrict CGRP-related "activities outside the collaboration"—specifically, the parties agreed not to directly or indirectly, themselves or through any Affiliates, conduct or participate in, or advise, assist, or enable any third party to conduct or participate in, the clinical development, commercialization, or manufacture of any inhibitor or modulator of CGRP, or CGRP receptor, other than the Amgen products the parties committed to develop and commercialize.

6. On April 21, 2017, Amgen and Novartis executed the 2017 Agreement to expand their collaboration so that Novartis would be involved in efforts to develop and commercialize erenumab within the United States. On the same date, the parties also signed Amendment No. 2 to the 2015 Agreement to include Canada within Novartis's commercialization territory, to

reconcile provisions of the two Collaboration Agreements and spell out their interrelationship, and to address other issues related to the parties' collaboration.

7. When the parties' expanded their relationship in 2017, Novartis intended to use (and is now using) the capabilities of Sandoz GmbH, a division of Novartis, to commercialize erenumab worldwide. Correspondingly, Amendment No. 2 revised the 2015 Agreement to make clear that Sandoz would be treated as an Affiliate for all purposes, including the restriction on "activities outside the collaboration." And Amendment No. 2 also specifically provided that the restriction on "activities outside the collaboration" would survive any earlier termination of the 2015 Agreement with respect to the collaboration efforts spelled out in the 2017 Agreement for the duration of the 2017 Agreement.

8. Unbeknownst to Amgen at the time the Collaboration Agreements were negotiated and executed, Sandoz had been actively involved since May 2015 in a contract manufacturing agreement ("CMA") with Alder BioPharmaceuticals to clinically develop, commercialize, and manufacture eptinezumab—an antibody that, like Amgen's erenumab, is designed to treat migraines by inhibiting the binding of CGRP to CGRP receptors.

9. Novartis never informed Amgen of the Sandoz-Alder CMA in 2017 when Amgen and Novartis negotiated and entered into Amendment No. 2 to the 2015 Agreement and the 2017 Agreement, despite specific discussions about Sandoz and agreement that Sandoz would be treated as an Affiliate for purposes of the Collaboration Agreements. Nor did Novartis inform Amgen of the Sandoz-Alder CMA when, in December 2017 and June 2018, Sandoz agreed with Alder to expand its participation in Alder's efforts to develop and commercialize eptinezumab.

10. In September 2018, Novartis confessed to Amgen that a few months earlier it had discovered the existence of a breach of the parties' Collaboration Agreements based on the Sandoz-

Alder CMA—which Novartis wrongly attempted to characterize as merely a "technical" breach. In response, Amgen, first informally and then formally, notified Novartis that Sandoz's manufacture of eptinezumab constituted a material breach of the Collaboration Agreements, and demanded that Novartis cure the breach within the specific period provided by the Collaboration Agreements.

11. In response to Amgen's notice of material breach and demand for cure, Novartis has not cured. It claimed that any breach was cured because on January 1, 2019 Sandoz and Alder agreed to amend their CMA to wrap up the manufacturing relationship ("CMA Amendment 5"). But, as Novartis admits, CMA Amendment 5 did not terminate the CMA before the end of the cure period provided by the Collaboration Agreements. To the contrary, in CMA Amendment 5 Sandoz agreed to provide Alder with a "Guaranteed Capacity" of eptinezumab each year from 2019 through 2023. Moreover, whereas under the CMA Sandoz originally had the right, in its discretion, to terminate the agreement by providing Alder notice, in CMA Amendment 5 Sandoz gave up that right as part of the amendment designed "to not jeopardize the launch of [eptinezumab]."

12. On February 22, 2019, Alder announced that it submitted to the FDA a Biologics License Application ("BLA")—a request for permission to commercialize a biologic product—for eptinezumab. A BLA requires significant information on manufacturing and controls that is developed through the pre-commercial manufacturing of the biologic product. Alder's February 22, 2019 BLA, in particular, is supported by significant information Sandoz developed and provided to assist Alder in developing and commercializing eptinezumab. Moreover, the CMA requires Sandoz to continue providing information and support to Alder in connection with its February 22, 2019 BLA. Alder claims that if its BLA is accepted and the FDA approves

eptinezumab, and with Sandoz's continuing manufacturing and other assistance, it will be on track for an early 2020 commercial launch.

13. In short, continuously from April 21, 2017 through the present—and for a period that may continue for up to five more years—Novartis's Affiliate Sandoz has been and will be directly involved in the manufacture and development of an Alder CGRP inhibitor, thus advising, assisting, and enabling Alder in the clinical development, commercialization, and manufacture of a Distracting Product in violation of the Collaboration Agreements. These efforts have positioned Alder to capture a share of the multi-billion-dollar market for CGRP inhibitor migraine therapies to Amgen's detriment.

14. As a result of Novartis's material breach, Amgen is entitled to terminate the Collaboration Agreements with Novartis and to recover damages.

THE PARTIES AND OTHER RELEVANT PERSONS

15. Amgen Inc. is a Delaware corporation with its principal place of business at One Amgen Center Drive, Thousand Oaks, California, 91320. Amgen is a biotechnology company that focuses on discovering, developing, manufacturing, and delivering innovative medicines. Amgen's medicines typically address diseases for which there are limited treatment options, using novel protein or other biological structures such as antibodies to address and beneficially affect the cellular or biochemical mechanisms associated with those diseases. Amgen developed erenumab, the first and only FDA-approved treatment specifically targeted to prevent migraines by blocking the calcitonin gene-related peptide receptor (CGRP-R), which is believed to play a critical role in migraines.

16. Defendant Novartis Pharma AG is a Swiss company with its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland, and an affiliate of the Novartis corporate family. Novartis holds itself out as being in the business of researching, developing, and

manufacturing patented treatments for cancer, cardio-metabolic diseases, immunology and dermatology diseases, ophthalmology diseases, neuroscience diseases, and respiratory diseases. Novartis's biopharmaceutical products are distributed and sold in the State of New York and throughout the United States.

17. Non-Party Sandoz GmbH is an Austrian company and has its principal place of business at Biochemiestraße 10, 6250 Kundl, Austria. Sandoz GmbH is one of the entities in Novartis's Sandoz division, and is an Affiliate of Novartis Pharma AG. Sandoz holds itself out as having "in-depth experience and expertise in biotech manufacturing," a "long and distinguished track record in custom manufacturing," "tried and trusted partnerships with global pharmaceutical companies," and "end-to-end expert support throughout the life of a project." As such, Sandoz sometimes partners with other pharmaceutical or biotechnology companies to provide finished pharmaceutical or biotechnology products.

18. Non-Party Alder Biopharmaceuticals, Inc., is a Delaware corporation with its principal place of business at 11804 North Creek Parkway South, Bothell, WA 98011. Alder is a biopharmaceutical company that claims to have developed a monoclonal antibody known as eptinezumab that, like erenumab, inhibits the ability of CGRP to bind with its receptors in a process that is believed to play a critical role in migraines.

JURISDICTION AND VENUE

19. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(a)(2) because the dispute involves parties with diversity of citizenship and the amount in controversy exceeds $75,000.

20. Pursuant to Section 16.3 of the 2015 Agreement and Section 15.3 of the 2017 Agreement, the parties have consented to the jurisdiction of state and federal courts of the State of New York and waived any defense that such is an inconvenient forum.

FACTS COMMON TO ALL CLAIMS

The 2015 Agreement

21. Effective August 28, 2015, the parties entered into the 2015 Agreement.

22. As stated in the Recitals of the 2015 Agreement, at that time, Amgen was "[d]eveloping its proprietary monoclonal antibody against calcitonin gene-related peptide (CGRP) receptor, known as AMG 334." AMG 334 is also known as erenumab, and is now known in some parts of the world by the brand name Aimovig®.

23. As stated in the Recitals of the 2015 Agreement, Amgen "wishe[d] to collaborate with Novartis, and Novartis wishe[d] to collaborate with Amgen, in each case with respect to the Development and Commercialization" of products that include erenumab.

24. As part of the 2015 Agreement, Amgen granted to Novartis and Novartis obtained from Amgen certain license rights to commercialize erenumab outside of the United States, Canada and Japan.

25. Among other covenants set forth in the 2015 Agreement, Section 7.2, titled Activities Outside the Collaboration, provides in part that "neither Party shall, itself or through its Affiliates, directly or indirectly conduct or participate in, or advise, assist or enable a Third Party to conduct or participate in, any Distracting Program."

26. Other provisions of the 2015 Agreement define the capitalized terms used in this restriction against "Activities Outside the Collaboration":

a. Novartis Pharma AG is one "Party" to the 2015 Agreement, as indicated in the Recitals of the 2015 Agreement.

b. Before Amendment No. 2, Section 1.2 of the 2015 Agreement defined "Affiliate" as follows:

> *"Affiliate"* means, with respect to a Party, any Person which controls, is controlled by or is under common control with such Party. For purposes of this definition and Section 1.139 only, "control" means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of 50% or more (or if less than 50%, the maximum ownership interest permitted by applicable Law) of the securities entitled to be voted generally or in the election of directors of such Person, or by contract or otherwise. For purposes of this Agreement, Sandoz shall be deemed not to be an Affiliate of Novartis.

(In 2017, the last sentence of Section 1.2, as set forth above, was deleted in connection with Amendment No. 2, as further described below.)

c. Section 1.154 of the 2015 Agreement defined Third-Party as "any entity other than a Party or an Affiliate of a Party." (This section was renumbered 1.163 in connection with Amendment No. 2.)

d. Section 1.37 of the 2015 Agreement defined a Distracting Program as "the clinical development, commercialization or manufacture of any Distracting Product." (This section was renumbered 1.42 in connection with Amendment No. 2.)

e. Section 1.36 of the 2015 Agreement defined a Distracting Product to include products—other than the Amgen products specifically identified as the subject of the collaboration—that inhibit or modulate CGRP or CGRP receptors. (This section was renumbered 1.41 in connection with Amendment No. 2.)

27. In Section 16.1 of the 2015 Agreement, the parties agreed that "Each Party shall have the right to exercise its rights and perform its obligations hereunder through its Affiliates …, *provided* that such Party shall be responsible for its Affiliates' performance hereunder."

Discussions Leading Up To Amendment No. 2 to the 2015 Agreement and the 2017 Agreement

28. In early 2017, Amgen and Novartis had several discussions about the possibility of expanding their relationship to include Novartis in efforts to commercialize erenumab in the United States.

29. On or about March 10, 2017, Amgen sent Novartis an initial draft amendment to the 2015 Agreement, which identified building blocks that Amgen regarded as essential to a deal over commercialization efforts in the United States. Among the provisions that Amgen flagged, Amgen highlighted that (a) Sandoz needed to be treated as an Affiliate for purposes of various sections of the 2015 Agreement, including specifically Section 7.2 (Activities Outside the Collaboration), and that the parties needed to discuss the treatment of Sandoz as an Affiliate; and, (b) Section 15.4 (Additional Surviving Provisions) needed to be amended so that the obligations of Section 7.2 would extend to and survive with respect to collaboration in the United States.

30. In response, Novartis confirmed that it was carefully reviewing the points that Amgen had raised.

31. Later, on or about April 9, 2017, Novartis provided Amgen with a draft amendment to the 2015 Agreement, in which Novartis proposed to delete the last sentence of Section 1.2 of the 2015 Agreement so that Sandoz would be treated as an Affiliate for all purposes.

32. While Amgen and Novartis specifically considered and discussed the treatment of Sandoz as an Affiliate, including under Section 7.2 of the 2015 Agreement, Novartis never informed Amgen that Sandoz was involved in a Distracting Program as described in that section. Nor did Novartis ever object to amending Section 15.4 to provide that the obligations of Section 7.2 would extend to and survive with respect to collaboration in the United States.

Amendment No. 2 to the 2015 Agreement

33. On April 21, 2017, the parties entered into Amendment No. 2 to the 2015 Agreement.

34. Among other things, in Section 2.6 of Amendment No. 2 the parties agreed that "[t]he last sentence of Section 1.2 of the [2015] Agreement is hereby deleted in its entirety." As noted above, that last sentence—which was deleted in Amendment No. 2—had provided that "For purposes of this Agreement, Sandoz shall be deemed not to be an Affiliate of Novartis."

35. Accordingly, effective April 21, 2017, Sandoz is recognized as an Affiliate of Novartis for purposes of the 2015 Agreement.

36. As amended by Amendment No. 2, the 2015 Agreement is—and is intended to be—interrelated with the 2017 Agreement.

37. For example, in Amendment No. 2, the parties agreed to add to the recitals of the 2015 Agreement the following language referencing the 2017 Agreement:

> "WHEREAS, Amgen and Novartis are parties to that certain Collaboration Agreement, dated April 21, 2017, with respect to the Commercialization of, and Medical Affairs Activities for, Franchise Product 1 in the United States (the '*US Collaboration Agreement*');"

And Section 1.168 of the 2015 Agreement, as amended by Amendment No. 2, defines the "US Collaboration Agreement" to have the meaning set forth in the Recitals. Accordingly, references to the "US Collaboration Agreement" in the 2015 Agreement as amended by Amendment No. 2 are to the same agreement referred to in this Complaint as the 2017 Agreement.

38. Furthermore, the 2015 Agreement, as amended by Amendment No. 2, also refers to the 2017 Agreement (using the defined term "US Collaboration Agreement") in at least the following Sections: Recitals, 1.38, 1.168, 3.2.5, 3.2.6, 3.5.3.1, 3.7, 3.8, 4.6, 4.8, 5.1, 5.4.5, 6.3, 7.4, 9.7.1, 9.7.2, 9.7.4, 9.11, 10.2.2, 10.3.2, 10.4.2, 10.6, 11.6.1, 12.3, 15.3.2, 15.4.

39. Among other things, one effect of these references to the 2017 Agreement was to call for obligations set forth in the 2015 Agreement to continue with respect to the 2017 Agreement. For example, Section 15.4 of the 2015 Agreement, as amended in 2017, provides that "[i]n addition to and without prejudice to the provisions of Section 15.3 (Effect of Termination) and the provisions that are expressly stated to survive termination, in the event of any expiration or termination of this Agreement the following provisions shall survive: . . . 7.2 (Activities Outside the Collaboration) through 7.4 . . . (inclusive) (solely in the event this Agreement expires or earlier terminates prior to the expiration or earlier termination of the US Collaboration Agreement, solely with respect to any Franchise Product 1 Distracting Program and solely for the term of the US Collaboration Agreement)."

The 2017 Agreement

40. On April 21, 2017, the parties also entered into the 2017 Agreement. Generally speaking, the 2017 Agreement sets forth the terms upon which the parties agreed to collaborate in commercializing erenumab in the United States.

41. The 2017 Agreement is—and is intended to be—interrelated with the 2015 Agreement.

42. For example, the recitals of the 2017 Agreement define the "Existing License Agreement" as "that certain Exclusive License and Collaboration Agreement, dated as of August 28, 2015, pursuant to which (i) the Parties are Developing the Product (as defined below) globally, and (ii) Amgen granted to Novartis and Novartis obtained from Amgen, certain license rights to commercialize the Product outside the United States, Canada and Japan." And Section 1.40 of the 2017 Agreement defines the "Existing License Agreement" to have the meaning set forth in the Recitals. In other words, references to the "Existing License Agreement" in the 2017 Agreement are to the same agreement referred to in this Complaint as the 2015 Agreement.

43. Moreover, in the Recitals, the 2017 Agreement states that "simultaneously herewith, the Parties are amending the Existing License Agreement . . . to amend, modify and restate certain conditions of the Existing License Agreement in connection with this Agreement."

44. Further, among other things, Section 15.6 of the 2017 Agreement provides as follows:

> Entire Agreement. This Agreement, including the attached Appendices, Schedules and Exhibits and the Safety Agreement and together with the Existing License Agreement, constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same.

45. And under the Definitions section, the 2017 Agreement provides that the "[c]apitalized terms herein that are not otherwise defined herein shall have the meanings ascribed to such terms in the Existing License Agreement [2015 Agreement]."

46. In addition, the 2017 Agreement makes reference to the 2015 Agreement (using the defined term "Existing License Agreement") in at least the following Sections: Recitals, 1.13, 1.40, 1.62, 1.78, 1.127, 2.2.4, 2.5, 2.7, 2.10, 3.6, 4.1, 4.2.1, 4.2.3, 4.2.5, 4.5, 5.6, 8.6.1.3, 8.6.3, 8.6.4, 8.9, 9.1.1, 9.2.5, 9.3.2, 9.4.7, 10.1, 10.3, 11.4, and 15.6.

47. In Section 15.1 of the 2017 Agreement, the parties agreed that "Each Party shall have the right to exercise its rights and perform its obligations hereunder through its Affiliates …, *provided* that such Party shall be responsible for its Affiliates' performance hereunder."

Sandoz's Involvement in Novartis's Performance of the Collaboration Agreements

48. At all times since April 21, 2017 (the effective date of the 2017 Agreement and Amendment No. 2 to the 2015 Agreement), Sandoz has been an Affiliate of Novartis under the terms of the Collaboration Agreements.

49. As set forth in Section 16.1 of the 2015 Agreement and Section 15.1 of the 2017 Agreement, Novartis has in various ways and from time to time used or relied on resources and

services of its Affiliate Sandoz, a Novartis division, in connection with exercising its rights and performing its obligations under the Collaboration Agreements.

The Sandoz-Alder Contract Manufacturing Agreement

50. On May 4, 2015, Sandoz and Alder entered into the Sandoz-Alder contract manufacturing agreement ("CMA"), wherein Sandoz agreed to manufacture ALD403 (eptinezumab) Bulk Drug Substance for Alder.

51. Eptinezumab is a monoclonal antibody that Alder claims acts to inhibit CGRP in its binding to CGRP receptors—*i.e.*, eptinezumab is a CGRP inhibitor.

52. On September 19, 2016, Sandoz and Alder amended the CMA (CMA Amendment 1) to expand the scope of work under the CMA to include Process Characterization Activities to be performed by Sandoz.

53. On November 17, 2016, Sandoz and Alder amended the CMA (CMA Amendment 2) to expand the scope of work under the CMA to include a Mock Run, or production activities related to the characterization of the downstream process, to be performed by Sandoz.

54. On December 22, 2017, Sandoz and Alder amended the CMA (CMA Amendment 3.1) to expand the scope of work under the CMA to include Validation Activities related to eptinezumab to be performed by Sandoz.

55. On June 15, 2018, Sandoz and Alder amended the CMA (CMA Amendment 4) to expand the scope of work under the CMA to include Ongoing Process Validation Activities to be performed by Sandoz.

56. Clause 31(1) of the CMA allowed "[e]ach Party [to] terminate the [CMA] upon its sole discretion . . . by giving the other party . . . prior written notice."

57. Based on the fact that Sandoz continuously maintained the CMA relationship with Alder since 2015, Amgen is informed and believes that after April 21, 2017 (the effective date of

Amendment No. 2 to the 2015 Agreement and the 2017 Agreement) Sandoz never exercised its right under Clause 31(1) of the CMA to "terminate [the CMA] upon its sole discretion . . . by giving the other party . . . prior written notice."

58. Effective January 1, 2019, Sandoz and Alder amended the CMA (CMA Amendment 5) by, among other things, adding a "Guaranteed Capacity" that Sandoz agreed to provide Alder each year from 2019 through 2023 "[t]o facilitate the completion and termination of the manufacturing relationship between [Sandoz and Alder] and in order to not jeopardize the launch of [eptinezumab]."

59. In CMA Amendment 5, among other things, Sandoz agreed to delete Clause 31(1) from the CMA, giving up the right it previously had to terminate the CMA in its discretion by providing notice to Alder.

60. CMA Amendment 5 contemplates that Sandoz will continue to supply Alder with eptinezumab from 2019 until at least 2023.

61. As Alder disclosed in its February 2019 10-K, "Sandoz's obligation to provide such guaranteed capacity extends through termination of the agreement on the earlier of (i) December 31, 2023 (but only if Sandoz has manufactured and delivered the guaranteed capacity) or (ii) the date that Sandoz has manufactured and delivered such guaranteed capacity."

Novartis Continuously and Materially Breaches the Collaboration Agreements Since April 21, 2017, Without Informing Amgen Until September 7, 2018

62. Alder is neither a Party to the Collaboration Agreements, nor an Affiliate of a Party to the Collaboration Agreements. Alder is therefore a Third Party under the terms of the Collaboration Agreements.

63. Between April 21, 2017 and the present, as set forth above, Sandoz has from time to time manufactured eptinezumab for Alder and provided other information and services to advise, assist, and enable Alder in developing, commercializing, and manufacturing eptinezumab.

64. Sandoz will for some period in the future continue to provide eptinezumab-manufacturing capacity for Alder, as well as other information and services to advise, assist, and enable Alder in developing, commercializing, and manufacturing eptinezumab.

65. Eptinezumab qualifies as a Distracting Product under Section 1.41 of the 2015 Agreement.

66. Accordingly, beginning as of at least April 21, 2017 (the effective date of Amendment No. 2 to the 2015 Agreement), Sandoz, a Novartis division, has continuously been engaged in, and will for several years in the future continue to be engaged in, a Distracting Program as defined by Section 1.42 of the 2015 Agreement.

67. Novartis never disclosed the existence of the Sandoz-Alder CMA to Amgen before or at the time of entering into the 2017 Agreement and Amendment No. 2 to the 2015 Agreement.

68. On September 7, 2018—nearly a year and a half after the effective date of Amendment No. 2 to the 2015 Agreement and the 2017 Agreement—Novartis for the first time informed Amgen of the Sandoz-Alder CMA.

Amgen Asserts Its Rights and Novartis Fails to Cure

69. Section 15.2.2 of the 2015 Agreement and Section 14.2.1 of the 2017 Agreement provide the following procedure in the event of a perceived material breach:

> If either Party believes that the other Party is in material breach of this Agreement, then such Party may deliver notice of such material breach (specifying the nature of the breach in reasonable detail) to the other Party. If the breaching Party (or its Affiliate) fails to cure such material breach within [a specified number of] days after the receipt of such notice (or [a specified number of] days with respect to any failure to pay amounts due hereunder), then the other Party shall be permitted to terminate this Agreement by written notice given within [a specified number of]

> days after the end of such cure period and effective upon delivery; *provided, however*, if the breaching Party notifies the other Party within such [specified] period that it disagrees in good faith with such asserted basis for termination, this Agreement shall not terminate unless and until the matter has been finally resolved in accordance with [the Governing Law and Jurisdiction provisions].

70. Amgen sent Novartis an official notice of material breach on November 29, 2018, which Novartis received through the delivery means specified by the Collaboration Agreements on or about December 3, 2018.

71. Novartis responded to Amgen's official notice of material breach on January 24, 2019 ("Novartis's Response").

72. In Novartis's Response, Novartis admitted that Sandoz is its Affiliate.

73. In Novartis's Response, Novartis admitted that the Sandoz-Alder manufacturing relationship commenced on May 4, 2015.

74. In Novartis's Response, Novartis admitted that Sandoz contracted with Alder to manufacture eptinezumab, and that it has done so.

75. In Novartis's Response, Novartis admitted that Sandoz will continue to provide manufacturing capacity for eptinezumab for up to five more years.

76. In Novartis's Response and thereafter, despite admitting to the various facts described above, Novartis disputed the propriety of Amgen terminating either the 2015 Agreement or the 2017 Agreement based on the Sandoz-Alder manufacturing relationship.

77. On April 2, 2019, Amgen sent Novartis a notice of termination that by its terms—and consistent with the provisions of Section 15.2.2 of the 2015 Agreement and Section 14.2.1 of the 2017 Agreement—will be effective if and when the matter is resolved as specified in the Governing Law and Jurisdiction provisions of the Collaboration Agreements.

FIRST CAUSE OF ACTION

Declaratory Judgment – Material Breach of Contract – Termination

78. Amgen realleges paragraphs 1 through 77 above.

79. This is a claim for declaratory judgment pursuant to 28 US.C. § 2201 for the purpose of resolving a justiciable controversy between Amgen and Novartis about whether Amgen is entitled to terminate the parties' Collaboration Agreements.

80. An actual, justiciable, controversy exists between Amgen and Novartis that warrants relief to declare the respective rights and obligations of the parties.

81. The 2015 Agreement and the 2017 Agreement are each valid, binding contracts between Amgen and Novartis.

82. Amgen has materially performed its obligations under the 2015 Agreement and the 2017 Agreement.

83. As set forth above, Novartis has materially breached the 2015 Agreement and the 2017 Agreement because its Affiliate Sandoz has provided and continues to provide manufacturing capacity to Alder for the clinical development, commercialization and manufacture of eptinezumab. Novartis has, therefore, directly conducted or participated in, or advised, assisted, or enabled Alder, a Third Party, to conduct or participate in a Distracting Program.

84. As set forth above, Novartis has failed to cure its material breach of the 2015 Agreement and the 2017 Agreement within the period specified by those agreements because, among other reasons, it admits that its Affiliate Sandoz will continue to provide manufacturing capacity to Alder for the clinical development, commercialization, and manufacture of eptinezumab for a period that will extend to December 31, 2023 and possibly beyond.

85. Pursuant to Section 15.2.2 of the 2015 Agreement and Section 14.2.2 of the 2017 Agreement, because Novartis has failed to cure a material breach of each of the agreements within

the specified period after notice from Amgen, Amgen is entitled to terminate the 2015 Agreement and the 2017 Agreement.

86. Notwithstanding its admissions, Novartis disputes that it has materially breached the 2015 Agreement and the 2017 Agreement, disputes that it has failed to cure such breach, and disputes that Amgen is entitled to terminate the 2015 Agreement and the 2017 Agreement.

87. Within the period specified in the Collaboration Agreements, Amgen has notified Novartis of Amgen's intention to terminate the Collaboration Agreements if and when the matter is resolved as specified in the dispute resolution procedures set forth in the Collaboration Agreements.

88. Amgen is entitled to judgment declaring that (a) Novartis materially breached the 2015 Agreement, (b) Novartis failed timely to cure its material breach of the 2015 Agreement, (c) Amgen is permitted to terminate the 2015 Agreement, and (d) upon entry of judgment, the 2015 Agreement is terminated.

89. Amgen is entitled to judgment declaring that (a) Novartis materially breached the 2017 Agreement, (b) Novartis failed timely to cure its material breach of the 2017 Agreement, (c) Amgen is permitted to terminate the 2017 Agreement, and (d) upon entry of judgment, the 2017 Agreement is terminated.

SECOND CAUSE OF ACTION

Breach of Contract – Damages for Breach

90. Amgen realleges paragraphs 1 through 77 above.

91. The 2015 Agreement and 2017 Agreement are each valid, binding contracts between Amgen and Novartis.

92. Amgen has materially performed its obligations under the 2015 Agreement and 2017 Agreement.

93. Novartis has breached the 2015 Agreement and the 2017 Agreement.

94. Novartis has not cured its breach of the 2015 Agreement and 2017 Agreement.

95. Novartis's breach of the 2015 Agreement and 2017 Agreement has caused, and will continue to cause, Amgen damages in an amount to be proven at trial, including, but not limited to, reducing erenumab's market advantage and diverting sales from erenumab to its competitor, eptinezumab.

THIRD CAUSE OF ACTION

Negligent Misrepresentation

96. Amgen realleges paragraphs 1 through 77 above.

97. The Sandoz-Alder CMA was not public before or at the time the parties negotiated and entered into Amendment No. 2 to the 2015 Agreement or the 2017 Agreement.

98. When the parties negotiated and entered into Amendment No. 2 to the 2015 Agreement and the 2017 Agreement, Amgen did not know and could not reasonably have known about the Sandoz-Alder CMA.

99. Relative to Amgen, Novartis had special access to information regarding whether its Affiliate Sandoz, a division of Novartis, was engaging in a Distracting Program as defined in the Collaboration Agreements.

100. Given the parties' relationship and their specific negotiations about treating Sandoz as an Affiliate for purposes of the Collaboration Agreements, in negotiating and entering into Amendment No. 2 to the 2015 Agreement and the 2017 Agreement, Novartis had (a) a duty to determine whether Sandoz, a division of Novartis, was engaging in a Distracting Program as defined in the Collaboration Agreements, and (b) a duty to disclose complete and accurate information to Amgen about whether Sandoz, a division of Novartis, was engaged in such a Distracting Program.

101. Amgen reasonably relied on Novartis to notify Amgen if any of Novartis's Affiliates were engaged in a Distracting Program before or at the time of entering into Amendment No. 2 to the 2015 Agreement or the 2017 Agreement.

102. Novartis negligently failed to determine and inform Amgen that its Affiliate Sandoz, a Novartis division, was engaging in a Distracting Program before or at the time of entering into Amendment No. 2 to the 2015 Agreement and the 2017 Agreement. In so doing, Novartis negligently misled Amgen to believe that neither Novartis nor its Affiliates was engaged in a Distracting Program as defined in the Collaboration Agreements.

103. Amgen's reliance on Novartis's silence about Sandoz's involvement in a Distracting Program was foreseeable.

104. As a result of Novartis's failure to disclose the existence of the Sandoz-Alder CMA before or at the time of entering into Amendment No. 2 to the 2015 Agreement or the 2017 Agreement, Novartis induced Amgen to expand the parties' contractual relationship that it would not have agreed to if the Sandoz-Alder CMA had been disclosed to Amgen, and to suffer damages in an amount that will be proven at trial, including sums associated with various sales of erenumab that were paid to or shared with Novartis as a result of having entered into the 2017 Agreement and Amendment No. 2 to the 2015 Agreement.

PRAYER FOR RELIEF

WHEREFORE, Amgen requests that the Court grant relief in Amgen's favor and against Novartis as follows:

1. Entering judgment for Amgen and against Novartis on each Count as asserted herein;
2. Awarding actual and compensatory damages as proven at trial;

3. Awarding pre- and post-judgment interest; and

4. Awarding such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Amgen hereby demands a trial by jury on all causes of action and/or issues so triable.

Dated: April 4, 2019

/s/ Brant W. Bishop, P.C.
Beth Wilkinson
Brant W. Bishop, P.C.
Eunnice Eun (motion for admission *pro hac vice* forthcoming)
D'Juan Jones (motion for admission to the Bar of this court forthcoming)
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